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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,755

03/29/2006

Hiroshi Fukushima

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KUBOVCIK & KUBOVCIK
SUITE 1105
1215 SOUTH CLARK STREET
ARLINGTON, VA 22202

EXAMINER

MARCETICH, ADAM M

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/573,755	Applicant(s) FUKUSHIMA ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,7 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Japan 2003-340851, filed on 30 September 2003 has been received. A priority date of 30 September 2003 is given to claims 1-4, 7, 10-16.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 September 2009 has been entered.

35 USC § 112, 6th Paragraph

3. Applicant has amended the claims from "separation display means" to "separation display section," and removed the language "means" from corresponding claims. Therefore 35 USC 112, 6th paragraph is no longer invoked.

Art Unit: 3761

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-4, 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sperko; William A. et al. (US 5910138) in view of Hustad et al. (US 5103979) in view of Brochman (US 3923198).

7. Regarding claims 1 and 7, Sperko discloses a medical container (col. 3, lines 21-37, col. 9, lines 60-67, Figs. 1, 2, container 10) comprising:

8. a separable partition wall section which is formed by heat-welding or bonding parts of container outer members opposed to each other (col. 7, lines 34-41, col. 17, lines 14-22, Figs. 1, 2, peelable seals 25, 26 formed by heated bars); and

9. the partition wall section being at least partially blocked or filled by contents in the medical container when the partition wall section is separated (col. 7, lines 54-61, Figs. 1, 2, seals 25, 26 ruptured to allow mixing). Examiner interprets the mixing and flow of

Art Unit: 3761

medication between the spaces of seals 25 and 26 as at least partially blocking a partition wall section, since particulate matter moves into the space between these seals during mixing (col. 8, lines 19-31, especially lines 28-31). Sperko discloses the invention substantially as claimed, see above. However, Sperko lacks a separation display section as claimed [1, 7]. Hustad discloses a package for hermetically sealing consumable products (col. 1, lines 8-15, col. 4, lines 9-28, especially lines 16-22), further comprising:

10. a separation display section (col. 4, lines 9-28, especially lines 16-22, col. 5, lines 40-55, Figs. 5-6, peel seal area 25);

11. said separation display section being visible from outside the container outer member opposed to the container outer member on which the separation display section is provided, prior to separation of the partition wall section (col. 6, lines 25-33, Figs. 10-11, transparent front panel 41 and opaque rear panel 42). To clarify, an opaque rear panel allows viewing only from a side opposed to the container outer member on which separation display means is provided.

12. One would be motivated to modify Sperko with the separation display section as taught by Hustad to ensure that mixing has occurred since Sperko calls for a transparent material that allows a user to inspect contents visually (col. 8, lines 19-31, especially lines 28-31). in other words, Sperko points out the importance of inspecting the contents of a mixing bag before dispensing to a patient. Hustad provides the advantage of indicating upon even casual examination when a package has been opened due to either tampering or normal use (col. 4, lines 9-15). Therefore, it would

Art Unit: 3761

have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko as discussed with the separation display means as taught by Hustad in order to allow quick examination of package.

13. Sperko in view of Hustad discloses the invention substantially as claimed, see above. However, Sperko in view of Hustad discloses only a separation display section printed directly on a separation display means (Hustad, col. 5, lines 7-20, peel seal area 25 and peel seal message indicia 27 formed by heat seal bar). Additionally, Sperko and Hustad lacks printing on an outer surface as claimed [claims 1 and 7]. To restate, Sperko and Hustad are silent regarding a separation display section provided or printed on an outer surface, and also lack a film as claimed [claim 7].

14. Brochman discloses a tape closure system having an opacifying layer and obscuring effect (col. 1, lines 44-46, 53-62, col. 3, lines 37-43), further comprising separation display means provided on an outer surface of a container (col. 4, lines 10-19, Fig. 1, indicator strip 16). Examiner interprets the limitation of "printing" on one of the container outer members broadly to include indicator strip 16 of Brochman as provided outside and bonded to layer 20. Brochman provides the advantage of simultaneously hermetically sealing an aperture and providing tamper indication (col. 4, lines 10-19, film 26 and adhesive 28 sealing aperture 12). This is valuable in the present invention since a bag containing separate medical products often require sealing an edge during manufacture. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko in view of Hustad as

Art Unit: 3761

discussed with the separation display means as taught by Brochman in order to simultaneously seal an opening and provide tamper indication.

15. Regarding the limitation of a separation display means “provided by printing,” Examiner notes that the claims are directed to a device, not necessarily the method of manufacturing. That is, Examiner compares the claimed structure of a separation display means with the peel seal area 25 of Hustad and indicator strip 16 Brochman, not the respective methods of manufacturing. Hustad embosses a readable design with a heated bar (col. 5, lines 7-20, especially lines 15-20, heat seal bar creating opacity condition indicia). This method is consistent with printing methods disclosed in the specification (p. 16, lines 8-14, especially line 9, “hot stamping”). Also, Brochman prints indicia with ink, consistent with methods from the specification (p. 16, l8-14, especially line 10, “ink jet printing”).

16. Regarding claims 2, 3, 10 and 11, Sperko discloses a medical container comprising:

17. [2, 10] outer members made of synthetic resin film (col. 8, lines 10-18, especially line 18, polymer films); and

18. [3, 11] wherein the medical container is a multiple-chamber container which has a separable partition wall section formed by heat-welding parts of films opposed to each other and has a plurality of chambers partitioned by the partition wall (col. 17, lines 14-22, Figs. 1, 2, peelable seals 25, 26 formed by heated bars and separating container into a plurality of chambers).

Art Unit: 3761

19. Regarding claims 4 and 12, Sperko discloses the invention substantially as claimed, see above. However, Sperko lacks separation display means as claimed [claims 4 and 12]. Hustad discloses:

20. a separation display section having a symbol display section (col. 6, lines 25-33, Figs. 10-11, message information 45); and

21. a symbol covering section provided outside the symbol display section (col. 6, lines 25-33, Figs. 10-11, rear panel 42); and

22. the symbol covering section covers the symbol display section such that the symbol display section cannot be visually recognized from outside the container outer member on which the separation display section is provided (col. 6, lines 25-33, Figs. 10-11, rear panel 42 disclosed as opaque and therefore preventing the symbol display section from being visually recognized from outside the container outer member on which the separation display means is provided). Hustad provides the advantage of allowing even minor openings of a peel seal to be detected (col. 6, lines 18-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Sperko as discussed with the separation display means as taught by Hustad in order to detect even minor openings of a peel seal.

23. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sperko; William A. et al. (US 5910138) in view of Hustad et al. (US 5103979) in view of Brochman (US 3923198), further in view of Porchia; Jose et al. (US 5564834).

Art Unit: 3761

24. Regarding claim 13, Sperko, Hustad and Brochman disclose the invention substantially as claimed, see above. However, these references lack printing on each of the container outer members as claimed [13]. Porchia discloses a thermoplastic bag with a closure (col. 1, lines 22-30, Fig. 1, bag 20), comprising:

25. a separable partition wall section (col. 3, lines 34-40, Fig. 2, closure arrangement 25); and

26. separation display sections on each of the container outer members (col. 7, lines 41-50, Fig. 19, interrupted portions 111a, 112a).

27. Porchia is silent whether interrupted portions 111a, 112a are printed on an outer surface of said partition wall section. Instead, Porchia discloses more broadly that the closure members are colored at certain intermittent or interrupted portions. In this rejection, Examiner cites Brochman as teaching printing on an outer surface of a partition wall section, and Porchia as demonstrating separation display sections on each of the container outer members.

28. Porchia clearly indicates whether a closure has been opened by forming a single line when closed, and an alternating line when opened (col. 7, lines 45-50). Here, Porchia provides an unambiguous signal showing whether a closure has been opened. Additionally, Porchia provides an indicator visible from both sides of a closure. One would be motivated to modify Sperko, Hustad and Brochman by providing separation display sections on each container outer members as taught by Porchia to indicate clearly whether a closure has been opened, and allow inspection from both sides.

Art Unit: 3761

29. Regarding claim 14, Sperko and Hustad disclose the invention as substantially claimed, and lack separation sections provided by printing on a film as claimed [14].

Examiner cites Brochman as teaching printing on a film as discussed for claims 1 and 7 above.

30. Regarding claims 15 and 16, Sperko discloses the invention as substantially claimed, but lacks a symbol covering section that prevents a symbol display section from being visually recognized from outside a container as claimed [15]. Hustad discloses a symbol covering section (col. 6, lines 25-33, Figs. 10-11, opaque rear panel 42) as discussed for claims 4 and 12 above.

31. Sperko, Hustad and Brochman disclose the invention as substantially claimed, but do not provide symbol display and covering sections on each separation display section. Examiner cites Porchia as demonstrating a plurality of at least symbol display sections. In other words, Porchia teaches alternating or intermittent displays that show whether a closure has been opened. See discussion of claim 13 above regarding rationale and motivation to modify Sperko, Hustad and Brochman in view of Porchia.

Response to Arguments

32. Applicant's arguments, see p. 7-9 filed 22 September 2009 with respect to the rejection(s) of claim(s) 1-4, 7 and 10-12 under 35 USC § 103 over Sperko, Hustad and Brochman have been fully considered but are not persuasive. Therefore, the rejection

Art Unit: 3761

is maintained. New claims 13-16 are rejected under 35 USC § 103 over Sperko, Hustad, Brochman and Porchia.

33. Applicant notes that each of Sperko, Hustad and Brochman fail to disclose or suggest separation display sections on each of the container outer members, as required by new claims 13-16. Examiner cites Porchia as teaching a plurality of alternating separation display sections in the new grounds of rejection.

34. Applicant asserts that the combination of Sperko, Hustad and Brochman fails to support a case of prima facie obviousness under 35 U.S.C. S 103(a) of the medical container recited in claims 1-4, 7 and 10-12. Applicant reasons that one would not have been motivated to modify Sperko according to the teachings of Hustad and Brochman, since Hustad discloses a seal that is clear when sealed but opaque when broken. Applicant finds that the opacity condition would at least partially obscure the contents of the container of Sperko in the broken seal area and prevent the contents from being capable of being visibly inspected as intended by Sperko. Examiner notes that the areas of text within message information 31, 32 or 35 become opaque, although surrounding areas may remain transparent. That is, an area remains transparent to allow the product to obscure visibility instead.

Art Unit: 3761

Conclusion

35. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

◆ Tanaka; Hiroshi et al. US 5501887

◆ Fukushima; H. et al. US 7293646

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to:

Adam Marcetich

Tel 571-272-2590

Fax 571-273-2590

37. The Examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
15 December 2009